

**Notice of Allowability**

Application No.

10/712,795

Examiner

Janet L. Epps-Ford

Applicant(s)

CROOKE ET AL.

Art Unit

1633

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Examiner's Amendment and Interview 7-09-08.
2. ☒ The allowed claim(s) is/are 127-145, 197-212 and 216-242.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 6-27-06; 8-25-06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 7-09-08.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Melissa R. Leuenberger-Fisher, Ph.D., J.D., on 7-09-2008.

The application has been amended as follows:

Claims 125-126 (Cancelled).

127. (Currently amended) ~~The antisense oligonucleotide of claim 125,~~ An antisense oligonucleotide 20 to 30 nucleobases in length, or a pharmaceutically acceptable salt form thereof, wherein the antisense oligonucleotide has a nucleobase sequence comprising the nucleobase sequence of SEQ ID NO:247.

128. (Currently amended) The antisense oligonucleotide of claim 127 ~~125~~, wherein the antisense oligonucleotide is 20 nucleobases in length and has a nucleobase sequence consisting of the nucleobase sequence of SEQ ID NO: 247.

129. (Currently amended) The antisense oligonucleotide of claim 127 ~~125~~, wherein the antisense oligonucleotide comprises at least one modified internucleoside linkage.

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131. (Currently amended) The antisense oligonucleotide of claim 127 ~~425~~, wherein the antisense oligonucleotide comprises at least one modified sugar moiety.

134. (Currently amended) The antisense oligonucleotide of claim 127 ~~425~~, wherein the antisense oligonucleotide is a chimeric oligonucleotide having a plurality of 2'-deoxynucleotides flanked on each side by at least one nucleotide having a modified sugar moiety.

137. (Currently amended) The antisense oligonucleotide of claim 127 ~~425~~, wherein the antisense oligonucleotide comprises at least one modified nucleobase.

139. (Currently amended) The antisense oligonucleotide of claim 127 ~~425~~, wherein the antisense oligonucleotide is a pharmaceutically acceptable salt form.

141. (Currently amended) A ~~composition~~ formulation comprising the antisense oligonucleotide of any one of claims ~~425-127~~ -140 and a pharmaceutically acceptable carrier or diluent.

142. (Previously presented) An antisense oligonucleotide 20 nucleotides in length having the sequence of nucleobases as set forth in SEQ ID NO:247 and comprising 5-methylcytosine at nucleobases 2, 3, 5, 9, 12, 15, 17, 19, and 20, wherein every internucleoside linkage is a phosphorothioate linkage, nucleotides 1-5 and 16-20 are 2'-O-methoxyethyl nucleotides, and nucleotides 6-15 are 2'-deoxynucleotides, or [a] wherein said antisense oligonucleotide is a pharmaceutically acceptable salt form thereof.

143. (Previously presented) The antisense oligonucleotide of claim 142, wherein the antisense oligonucleotide is [a salt form] said pharmaceutically acceptable salt form.

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144. (Previously presented) The antisense oligonucleotide of claim 143, wherein the pharmaceutically acceptable salt form is a sodium salt form.

145. (Currently amended) A ~~composition~~ formulation comprising the antisense oligonucleotide of any of claims 142 - 144 and a pharmaceutically acceptable carrier or diluent.

197. (Currently amended) An antisense compound 12 to 30 nucleobases in length and fully complementary to SEQ ID NO:3, wherein said compound ~~is targeted~~ specifically hybridizes to the range of nucleotides 3230-3287 as set forth in SEQ ID NO:3, or a pharmaceutically acceptable salt thereof.

212. (Currently amended) A ~~composition~~ formulation comprising the antisense compound of any one of claims 197-211 and a pharmaceutically acceptable carrier or diluent.

Claims 216-220 (Canceled).

221. (Currently amended) A ~~composition~~ formulation comprising the antisense oligonucleotide of claim ~~425-127~~ and a penetration enhancer.

222. (Currently amended) The ~~composition~~ formulation of claim 221, wherein the penetration enhancer is capric acid or lauric acid.

223. (Currently amended) A ~~composition~~ formulation comprising the antisense oligonucleotide of claim ~~425-127~~ and at least one additional pharmaceutically active material.

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224. (Currently amended) The ~~composition~~ formulation of claim 223, wherein the at least one additional pharmaceutically active material ~~therapeutic agent~~ is an anti-inflammatory agent.

225. (Currently amended) The ~~composition~~ formulation of claim 145, further comprising at least one additional pharmaceutically active material.

226. (Currently amended) The ~~composition~~ formulation of claim 225, wherein the at least one additional pharmaceutically active material ~~therapeutic agent~~ is an anti-inflammatory agent.

234. (Currently amended) The ~~composition~~ formulation of claim 233, wherein the penetration enhancer is capric acid or lauric acid.

235. (Currently amended) A ~~composition~~ formulation comprising the antisense oligonucleotide of claim 197 and at least one additional pharmaceutically active material.

236. (Currently amended) The ~~composition~~ formulation of claim 235, wherein the at least one additional pharmaceutically active material ~~therapeutic agent~~ is an anti-inflammatory agent.

237. (Currently amended) The antisense oligonucleotide of claim 133, wherein the bicyclic sugar moiety has a  $(-CH_2-)_n$  group forming a bridge between the 2' oxygen [ant] and the 4' carbon atoms of the sugar ring, wherein n is 1 or 2.

238. (Currently amended) The antisense oligonucleotide of claim 136, wherein the bicyclic sugar moiety has a  $(-CH_2-)_n$  group forming a bridge between the 2' oxygen [ant] and the 4' carbon atoms of the sugar ring, wherein n is 1 or 2.

239. (Currently amended) The antisense oligonucleotide of claim 204 wherein the bicyclic sugar moiety has a  $(-CH_2-)_n$  group forming a bridge between the 2' oxygen [ant] and the 4' carbon atoms of the sugar ring, wherein n is 1 or 2.

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240. (Currently amended) The antisense oligonucleotide of claim 207 wherein the bicyclic sugar moiety has a  $(-CH_2-)_n$  group forming a bridge between the 2' oxygen [ant] and the 4' carbon atoms of the sugar ring, wherein n is 1 or 2.

241. (New) A formulation comprising the antisense oligonucleotide of claim 142 and a penetration enhancer.

242. (New) The formulation of claim 241, wherein the penetration enhancer is capric acid or lauric acid.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner, Art Unit 1633

/J. L. E./  
Primary Examiner, Art Unit 1633

<b><i>Application Number</i></b> 	<b>Application/Control No.</b>	<b>Applicant(s)/Patent under Reexamination</b>	
	10/712,795	CROOKE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Janet L. Epps-Ford	1633	